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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,768

12/05/2003

Peter M. Bonutti

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7590

08/08/2006

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EXAMINER

THALER, MICHAEL H

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/729,768		BONUTTI, PETER M.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Michael Thaler		3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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Claims 23-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on Feb. 18, 2005.

Claims 15-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon, in figure 3, discloses shaft 56 and inflatable bladder 57 which has an eccentric shape upon inflation and cannula 5. Alternatively, the inflatable bladder 57 in figure 4 has the shape of a wedge since it tapers in the proximal direction. The Sheldon bladder, when inflated and axially moved with respect to the cannula, is inherently capable of separating adjacent layers of tissue since the bladder is made of the very strong inelastic material of Mylar (col. 8, lines 55-58) and is filled with a substantially non-compressible material which is liquid (the fluid in the phrase "fluid or gas" referred to in col. 8, line 68) which is substantially non-compressible. Alternatively, it would have been obvious that the Sheldon device creates a working space for the reasons set forth above. Cannula 5 has an opening at a proximal end portion, an opening at a distal end portion and defining a passage "therethrough" when it is expanded as

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described in col. 3, lines 19-36. As to claim 16, Mylar (col. 8, lines 55-58) does not stretch when fully inflated. As to claim 19, shaft 56 is rigidified when attached to rigid shaft 2 (col. 2, lines 39-40 and 60-63).

Claims 15-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Froning (3,875,595). Froning discloses shaft 47, 48, inflatable bladder 46 which has an eccentric shape upon inflation (since the portion on one side of the longitudinal axis of shaft 47, 48 is larger than the portion on the other side of the longitudinal axis) and cannula 31. The Froning bladder, when inflated and axially moved with respect to the cannula, is inherently capable of separating adjacent layers of tissue since the bladder is made of material which is sufficiently strong to hold fluid under pressure (col. 3, lines 17-21) and is filled with a substantially non-compressible material (the water described in col. 3, lines 17-21). Alternatively, it would have been obvious that the Froning device is capable of creating a working space for the reasons set forth above. As to claim 16, stretching of bladder 46 will be finished when it is fully inflated. As to claim 19, portion 48 of the shaft is rigid.

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Applicant's arguments filed June 7, 2006 have been fully considered but they are not persuasive.

The allegation that Sheldon fails to disclose a cannula having a passage that receives the shaft to deploy the bladder at a target site in tissue is unfounded. Sheldon clearly discloses a cannula (the needle 5) having a passage that receives the shaft (the spinescope 7) noting col. 3. lines 10-13 and figure 1. Further, even when the shaft and bladder are within the needle with the distal end of the shaft and the bladder at the distal end of the needle (in the manner similar to that shown in figure 1), the bladder is deployed "in tissue" as claimed since the entire assembly is within the body and is thus "in tissue". Further, the bladder is at a target site in tissue since the intended location within the distal end of the needle as described in col. 3, lines 10-13 is a target site. In any event, Sheldon, in col. 9, lines 59-70, indicates that the spinescope with a bladder is inserted into a smaller needle to enter the extra-dural space, indicating that the smaller needle has an open distal end to permit such entry. Further, contrary to appellant's remarks, Sheldon, in col. 3, lines 6-10 indicates that the tip 5b consists only of the bottom wall 5c and side walls 5d and has no closing wall above bottom wall 5c. Thus, the open distal end above the bottom wall 5c is inherently

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capable of enabling the passage of the shaft 7 therethrough, particularly when the halves 6 and 6a are spread apart as described in col. 3, lines 28-33.

The Froning bladder 46 is inherently capable of separating adjacent layers of tissue upon inflation since it provides a relatively large outward force when it inflates, and since only a relatively small force is required to separate adjacent layers of tissue.

The Froning bladder 46 provides a relatively large outward force when it inflates for the following reason: Inflation of the Froning bladder 46 would inherently apply a relatively large outward pressure against the opposed surfaces to retract them since the insertion of the inflation water under pressure into the bladder (col. 3, lines 17-20) would necessarily force the walls of the bladder outwardly to expand it and any surrounding tissue, particularly since water is a substantially incompressible material.

Only a relatively small force is required to separate adjacent layers of tissue to create a working space for the following reason: The type of tissue is not defined in the claims. The layer skin of a person is easily separated from the layer of the tissue forming the organs underlying the skin (e.g. in the stomach area). For example, a person can easily grasp

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and pull the skin overlying the stomach to separate the skin from the stomach and other tissue underlying the skin.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the

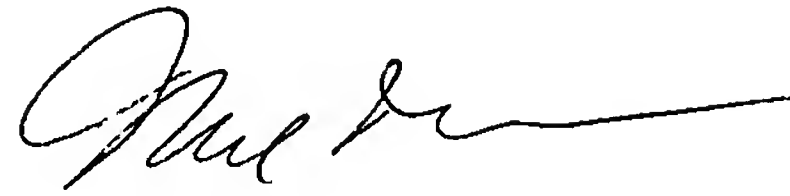
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organization where this application or proceeding is assigned is  
(571)273-8300.

mht  
8/4/06

A handwritten signature in black ink, appearing to read "Michael Thaler", with a long horizontal flourish extending to the right.

MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731